REMARKS

In th Sp cification:

The Examiner objected to the disclosure under MPEP § 608.01 because it contains embedded hyperlinks and/or other forms of browser-executable code. Per the Examiner's request, and in compliance with MPEP § 608.01, Applicant has deleted the embedded hyperlinks and/or other forms of browser-executable code. Therefore, Applicant respectfully requests that this ground of objection be withdrawn.

In the Claims:

Claims 1-24 are cancelled herein without prejudice or disclaimer.

Claims 25-28 are amended to clarify that the recited polypeptide inhibits neoplastic growth in tumor cells. No new matter is added by this amendment, which is supported in the specification beginning at page 138, line 13. In addition, the amendments to Claims 25-28 clarify that the claimed polypeptide does not have an extracellular domain.

Claim 33 is amended to depend from Claim 25.

Claims 35-37 are newly added herein. New Claims 35-37 do not encompass new matter. New Claims 35-36 are supported at pages 59-62 of the specification. New Claim 37 is supported in the specification beginning at page 138, line 13.

Oath/Declaration

The oath or declaration was defective because of a non-dated, non-initialed change to the address of inventor Dan L. Eaton. Dan L. Eaton was removed from this application pursuant to a 37 CFR § 1.48(b) letter filed on 9 December 2003. Therefore, the oath and declaration currently on file are compliant with 37 CFR § 1.67(a).

Potential Doubl Patenting:

The Examiner noted that SEQ ID NO: 42 of the instant application is identical to SEQ ID NO: 362 in other filings by Applicant and raised a question regarding double patenting. Pursuant to 37 CFR § 1.105 as cited by the Examiner, Applicant avers that, to the best of its knowledge, no claims of the present application conflict with claims presented in applications containing SEQ ID NO: 362.

Claim Rejections:

35 U.S.C. § 102

Claims 22-34 were rejected under 35 U.S.C. § 102(e) as being anticipated by Sheppard et al., U.S. Patent No. 6,197,930. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.01. As amended, all claims of the present application recite – or depend from claims that recite – a functional limitation not found in the Sheppard patent. Specifically, the claimed polypeptide inhibits neoplastic growth in tumor cells. The Sheppard reference does not teach this element and therefore does not anticipate the claims currently before the Examiner. Hence, Applicant submits that the grounds for the anticipation rejection have been overcome and request that the Examiner withdraw the § 102 rejection.

35 U.S.C. § 112, second paragraph

Claims 22-34 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states that the recitation of an extracellular domain in these claims is indefinite since the amino acid sequence set forth in SEQ ID NO: 42 is a soluble protein and is not disclosed as being expressed on a cell surface. Claims 22-24 and 29-31 are cancelled in the present paper. Applicant has amended

currently pending Claims 25-27 to clarify that the polypeptide encoded by the claimed nucleic acid does not comprise an extracellular domain. The Examiner's rejection of Claims 28 and 32-34 was based on their depending from rejected claims; therefore, the amendments to Claims 25-27 cure the alleged indefiniteness of Claims 28 and 32-34.

Accordingly, Applicant submits that it has overcome the rejection for indefiniteness of pending Claims 25-28 and 32-36, and requests that the rejection to those claims be withdrawn.

35 U.S.C. § 112, first paragraph

The Examiner has rejected Claims 22-26 and 33-34 under 35 U.S.C. § 112, first paragraph, alleging that they fail to satisfy the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. However, the Examiner does note that the amino acid sequence set forth in SEQ ID NO: 42 meets the written description requirement of 35 U.S.C. § 112, first paragraph. This sequence is encompassed in Claims 27-28 and 32, which were not rejected for lack of written description.

Applicant respectfully disagrees with the Examiner's statement that the written description requirement has not been satisfied for Claims 22-26 and 33-34. As the Examiner notes, the written description requirement requires that an applicant's specification convey with reasonable clarity to those skilled in the art, that as of the filing date sought, he or she was in possession of the invention. *Vas-Cath, Inc. v. Mahurkar,* 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). A written description of an invention involving a chemical genus requires a precise definition, such as by structure, formula . . . of the claimed subject matter ***sufficient to distinguish it from other materials***. *Univ. of Calif. v. Eli Lilly & Co.,* 43 USPQ2d 1398, 1405 (Fed. Cir. 1997) (emphasis added). Since one skilled in the art can distinguish a described formula from other formulas and therefore can ***identify many of the species*** that the claims encompass, a described

formula is normally an adequate description of the claimed invention. *Id.* at 1406 (emphasis supplied). Moreover, as noted in the Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, first paragraph, "Written Description" Requirement ("the Guidelines"), "[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." 66(4) *Fed. Reg.* at 1107; 191 USPQ at 97, (emphasis supplied).

Compliance with the written description requirement does not require an applicant to describe exactly the subject matter claimed; rather, the description must clearly allow a person of ordinary skill in the art to recognize that he or she invented what is claimed. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The test is whether the originally filed specification reasonably conveys to a person having ordinary skill in the art that applicant had possession of the subject matter later claimed. *In re Kaslow*, 217 USPQ 1089 (Fed. Cir. 1991). Moreover, in order to have possession of members of a claimed genus, the specification ***need not*** describe all of the species that the genus encompasses. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991).

In view of the legal standard regarding the written description requirement under 35 U.S.C. § 112, first paragraph, in combination with the interpretation of the written description requirement by the United States Patent and Trademark Office as set forth in the Guidelines, the instant specification satisfies the written description requirement because it would be clear to one of skill in the art that Applicant possessed the claimed subject matter at the time of filing the instant application.

Specifically, the Examiner rejects Claims 22-26 and 33-34 for lack of written description because the claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing features. Further, the Examiner asserts that the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

First, Applicant has cancelled Claims 1-24 and 29-31 without prejudice or disclaimer. Claims 25-26 and 33-34 have been amended to clarify that they are directed to polypeptide sequences with at least 95% sequence identity to SEQ ID NO: 42, wherein the polypeptide inhibits neoplastic growth in tumor cells. Therefore, the amended claims are not drawn to a genus of polypeptides defined only by sequence identity, but rather to a genus defined by sequence identity correlated with function.

Further, Applicant discloses structural features of the claimed sequences. For example, Figure 18 discloses several structural features including a signal sequence, N-myristoylation sites, and a cell attachment sequence. Page 102, beginning at line 6, explains a method of making the claimed sequence and page 138, beginning at line 13, describes the function of the claimed sequences, inhibiting neoplastic growth of tumor cells.

The analysis for determining whether the present specification provides written description support for the invention defined by Claims 25-26 and 33-34 may be performed by numerous methods, several of which are described in the Guidelines and further exemplified in the Revised Interim Written Description Guidelines Training Materials ("Written Description Training Materials"), published on the USPTO website at http://www.uspto.gov/web/offices/pac/writtendesc.pdf. These Written Description Training Materials are designed to provide additional clarity to the Guidelines which are published in the Federal Register, Volume 66, No. 4, pages 1099-1111. In fact, as indicated in the USPTO press release of March 1, 2000 introducing the Written Description Examination Training Materials (Press Release #00-15), these training materials were promulgated by the USPTO and are:

> "designed to aid PTO's patent examiners in applying the interim written description and utility guidelines in a uniform and consistent manner to promote the issuance of high quality patents. The training materials will also assist patent applicants in responding to the PTO when utility or written description issues are raised during the examination of a patent application." (emphasis added)

With regard to Claims 25-26 and 33-34, the present situation is analogous to Example 14 on pages 53-55 of the Written Description Training Materials. More specifically, in

Example 14 on pages 53-55 of the enclosed Written Description Training Materials, a claim directed to a protein and variants thereof having 95% sequence identity, all of which share the same biological function, is analyzed for its compliance with the written description requirement of 35 U.S.C. § 112, first paragraph. The Written Description Training Materials conclude that such a claim satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, when (1) a single protein sequence is actually reduced to practice, (2) procedures for making variants of that "reduced to practice" protein sequence are conventional in the art, and (3) an assay is described which allows identification of other proteins having the same biological activity. The reasoning provided by the USPTO in the Written Description Training Materials is that:

> "[t]here is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO:...does not have substantial variation since all of the variants must possess the specified [biological function] and must have at least 95% identity to the reference sequence, SEQ ID NO:...The single species disclosed ***is representative of the genus*** because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:...which are capable of the specified [biological function]. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by members of the genus.....{As such], the disclosure meets the requirements of 35 U.S.C. § 112, first paragraph, as providing adequate written description for the claimed invention." (emphasis added).

Analogous to Example 14 of the Written Description Training Materials, the present specification discloses and actually reduces to practice a polypeptide recited in Claims 25-26 and 33-34 (*i.e.*, SEQ ID NO: 42). Moreover, the polypeptide variants encompassed within Claims 25-26 and 33-34 ***do not have substantial variation*** with SEQ ID NO: 42 because (a) they share at least 95% to 99% sequence identity with

SEQ ID NO: 42 (Applicant notes that methods for routinely determining amino acid sequence identity are described in detail in the present specification at page 23, line 34 to page 29, line 2, *see also* pages 34-54), and (b) they share the biological function of inhibiting neoplastic growth of tumor cells. (Applicant further notes that the specification describes in detail in Example 30 a routine assay that is useful for identifying polypeptides having this biological function). As such, the polypeptides encompassed within Claims 25-26 and 33-34 all share substantial common structural features (*i.e.*, 95% to 99% sequence identity) and substantial common functional features (*i.e.,* ability to inhibit neoplastic growth in tumor cells). By implication, this is true for the claims depending from Claims 25-26 as well.

Moreover, the present specification also describes conventionally known methods known and used in the art for preparing a multitude of variants (see the present specification at page 59, line 13 to page 63, line 36).

Given the above, currently pending Claims 25-28 and 33-34 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph because the specification provides "a precise definition, such as by structure, formula ... of the claimed subject matter *sufficient to distinguish it from other materials*" as required by the Federal Circuit in *Univ. of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). Moreover, Claims 25-26 are analogous to the claim found to satisfy the written description requirement in Example 14 of the enclosed Written Description Training Materials. As such, under the Guidelines and the examination training materials promulgated by the USPTO for ensuring consistent examination of written description compliance during prosecution of patent applications, the written description requirement of 35 U.S.C. § 112, first paragraph, is satisfied for Claims 25-28 and 32-34. Therefore, Applicant respectfully requests this ground of rejection be withdrawn.

CONCLUSION

Currently pending Claims 25-28 and 32-37 are patentable. Applicant respectfully requests the Examiner grant early allowance of this application. The Examiner is invited to contact the undersigned attorney for the Applicant via telephone if such communication would expedite this application.

Respectfully submitted,

C. Noel Kaman

C. Noel Kaman
Registration No. 51,857

Attorney for Applicant

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200